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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/450,609 | 11/30/1999 | HELLE WEIBEL | DRF 3.0-051 | 7926 |

45776 7590 02/07/2007

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| EXAMINER | |
|---|---|
| KIM, JENNIFER M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|---|---|---|
| 3 MONTHS | 02/07/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/450,609 | WEIBEL ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer Kim | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *6,7,9,11-13,16 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,9,11-13,16 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The response filed October 10, 2006 have been received and entered into the application.

### Action Summary

Applicant's arguments filed October 10, 2006, with respect to the rejection(s) of claim(s) 6,7,9,11,12,13,16 and 28 under Lohray et al. (WO 9741097) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection and an objection are made as in this Office Action. Accordingly, allowability of claims 29-31 has been withdrawn and this Office Action is made non-final.

### *Claim Objections*

Claims 6, 7, 9, 11-13, 16, 28-31 are objected to because of the following informalities: It appear that active agent to be utilized is misspelled. It appears that claim 6, line 1, "5-[[4-**[13**-Methyl]- " should be "5-[[4-**[3**-Methyl-" . In claim 6 there are two periods at the end of the claim.

Claim 29 is objected to because it is missing a period at the end of the claim.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, 9, 11-13, 16 and 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "**low**" in claims 6 and 11, and the terms "**very low**" in claim 12 are relative terms, which renders the claim indefinite. The terms "**low**" and "**very low**" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonable appraised of the scope of the invention. The terms are indefinite since the "**low**" water content and "**very low**" water contents vary among the one of ordinary skill in the art.

The remaining claims 7, 9,13, 16 and 28-31 are indefinite to the extent that they depend from claims 6 and/or 11 and/or 12.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 7, 9, 11, 12, 13, 16, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (WO 9741097) of record in view of Staniforth et al. (U.S.Patent No. 6,866,867 B2) and further in view of Van Leverink (U.S.Patent No. 4,280,997).

Lohray et al. at page 34, lines 27-29, page 35, example, and page 7, lines 13-14, teach pharmaceutical composition comprising applicants' active agent, **5-[[4-3-Methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-methyl]thiazolidine-2,4-dione**, can be formulated in **tablet, capsule**, or **powder form** (dry form), and can combined with the pharmaceutically acceptable excipient such as **magnesium stearate**, **lactose**, carboxymethyl **cellulose**, **corn starch**, **flavourants, sweeteners**, and other media normally employed in preparing such compositions. Lohray et al. teach that the above composition typically contains from 1 to 20% by weight of active compound, and the remainder of the composition being pharmaceutically acceptable carrier, diluents or solvents. (page 35, lines 1-3).

Lohray et al. do not expressly teach the composition as being **low water** content comprising **anhydrous lactose** and **microcrystalline cellulose** and proportions of excipients set forth in claim 9 and formulating tablet by **direct compression** set forth in claim 28.

Van Leverink teaches that it is known that **anhydrous lactose** is very suitable as diluents in tablets. (column 1, lines 33-35). Van Leverink reports that when manufacturing tablets and capsules in pharmaceutical industry, the use of the **lactose** is

important and it is generally known that the presence of **moisture** in any form in tablets capsules may have a negative influence upon the quality of the tablets for capsules because the **water reacts** with the active ingredient in the tablet or the capsules. (column 1, lines 12-15).

Staniforth et al. teach that **microcrystalline cellulose** has been utilized extensively in the pharmaceutical industry as a **direct compression** vehicle for **solid dosage forms**. Staniforth et al. teach that **microcrystalline cellulose** is commercially available and compared to other **directly compressible** excipients, it is generally considered to **exhibit superior** compressibility and disintegration properties. (column 2, lines 44-53).

It would have been obvious to one of ordinary skill in the art to modify Lohray tablet composition comprising lactose in general, and employ anhydrous lactose because it is known that anhydrous lactose is very suitable as a diluents in tablet because it is generally known that when manufacturing tablets in pharmaceutical industry, that the presence of moisture in any form in tablet have a negative influence upon the quality of the tablet due the water reacting with the active ingredients as well known by Van Leverink. One would have been motivated to employ anhydrous lactose to obtain very low content of water of Lohray's tablet composition in order to achieve a quality tablet formulation lack moisture in order to avoid the negative influence upon the quality of the tablets well known by Van Leverink.

It would have been obvious to modify the Lohray's tablet composition to employ microcrystalline cellulose by direct compression in formulating the tablet because

Staniforth et al. teach that microcrystalline cellulose is generally considered to exhibit superior compressibility and disintegration property and it was been utilized extensively in the pharmaceutical industry to formulate solid dosage forms. One would have been motivated to employ microcrystalline cellulose in Lohray's composition in order to achieve an expected benefit of having superior disintegration properties of tablet formulated with superior compressibility with known direct compression technique. The proportions of active agents to be used set forth in claim 9 is deemed obvious because it is within the knowledge of the skilled pharmacologist to optimize the range of amounts of active agents and the excipients to be utilized. Moreover, Lohray et al. teach the ranges of 1-20% as being an active compound and the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents. One of ordinary skill in the art would optimize this range of excipients within the range of about 20-80% as taught by Lohray et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 6, 7, 9, 11-13, 16 and 28-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/699043. Although the conflicting claims are not identical, they are not patentably distinct from each other because the composition of instant invention encompasses the composition of the copending Application. The instant claims and the claims in the copending Application overlaps because each claiming a pharmaceutical composition comprising same active agent, same excipient constitute with having low water content.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 6, 7, 9, 11-13, 16 and 28-31 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,710,050. Although the conflicting claims are not identical, they are not

patentably distinct from each other because the process of preparing a pharmaceutical composition comprising the instant compound having the instant water content renders the instant composition obvious because the process of making the instantly claimed composition in the '050 patent will naturally lead to the present composition.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
January 23, 2007